

M E M O R A N D U M

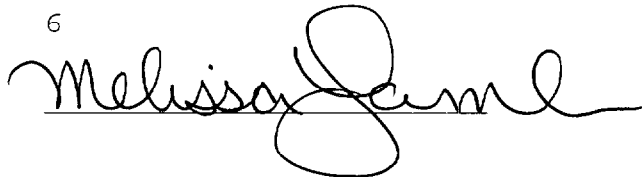
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

5503 '00 MAR 22 A10:16

Date: February 24, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Electronic Submission Update

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Electronic Submission Update
Presented for: Trades Meeting
Date Presented: 2/24/200
Presented by: Richard Sponaugle
Number of Pages: 6

A handwritten signature in cursive script, appearing to read "Melissa Lamb", written over a horizontal line.

Attachment

908-0308

M 680



Electronic Submission Update

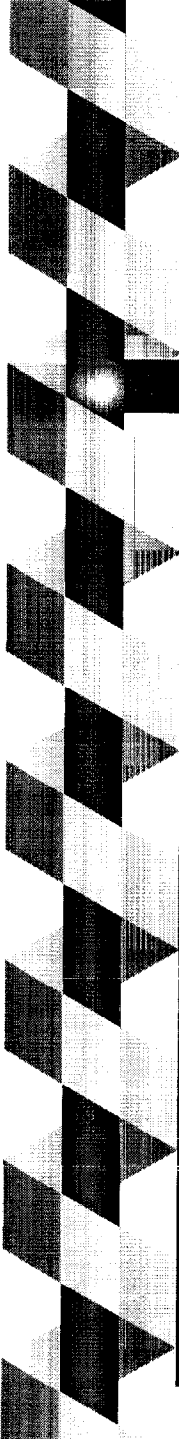
Richard Sponaugle

Computer Specialist

Senior Systems Engineer -

Electronic Submissions

Office of Generic Drugs



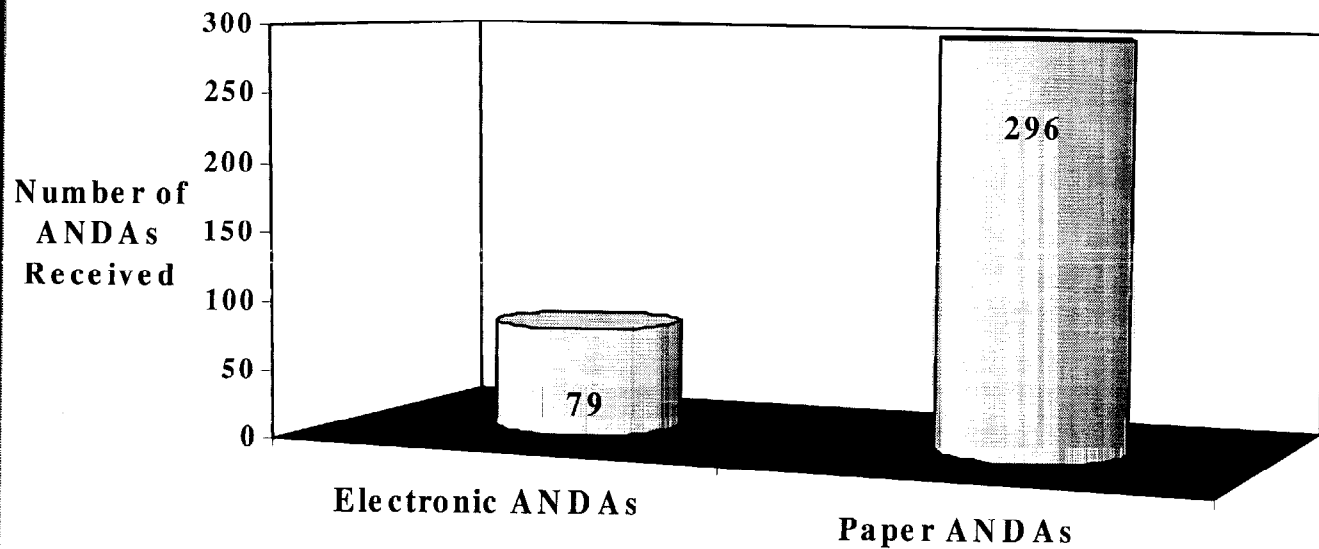
Electronic Submission -Participation Statistics

	<u>1999</u>	CMC <u>1998</u>	<u>1997</u>
Total Receipts For Year	55	44	0
		Bioequivalence	
	<u>1999</u>	<u>1998</u>	<u>1997</u>
Total Receipts For Year	44	32	10

Electronic Submission -Participation Statistics

Total ANDA Receipts CY 1999

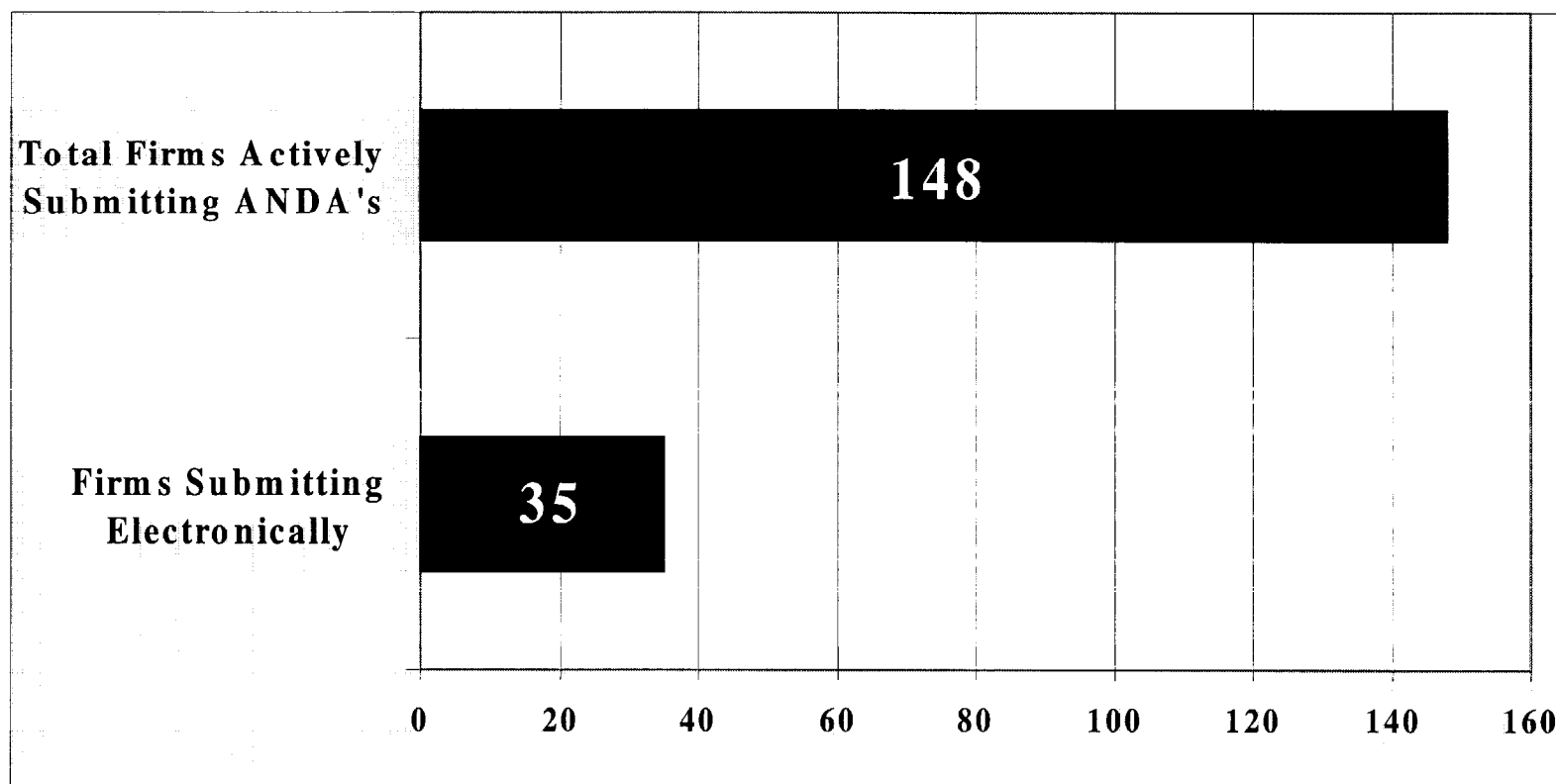
Twenty-seven percent of all ANDAs received by OGD in 1999 included some portion in an electronic format



Electronic Submission -Participation Statistics

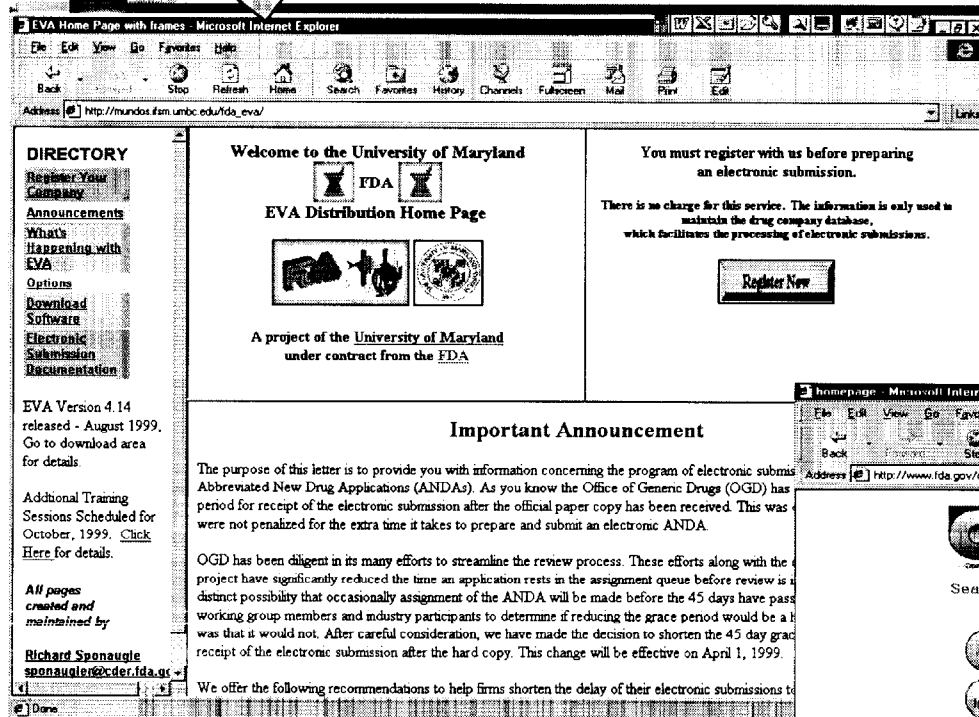
Number of Firms Participating

Twenty-Four percent of active firms are submitting electronically.

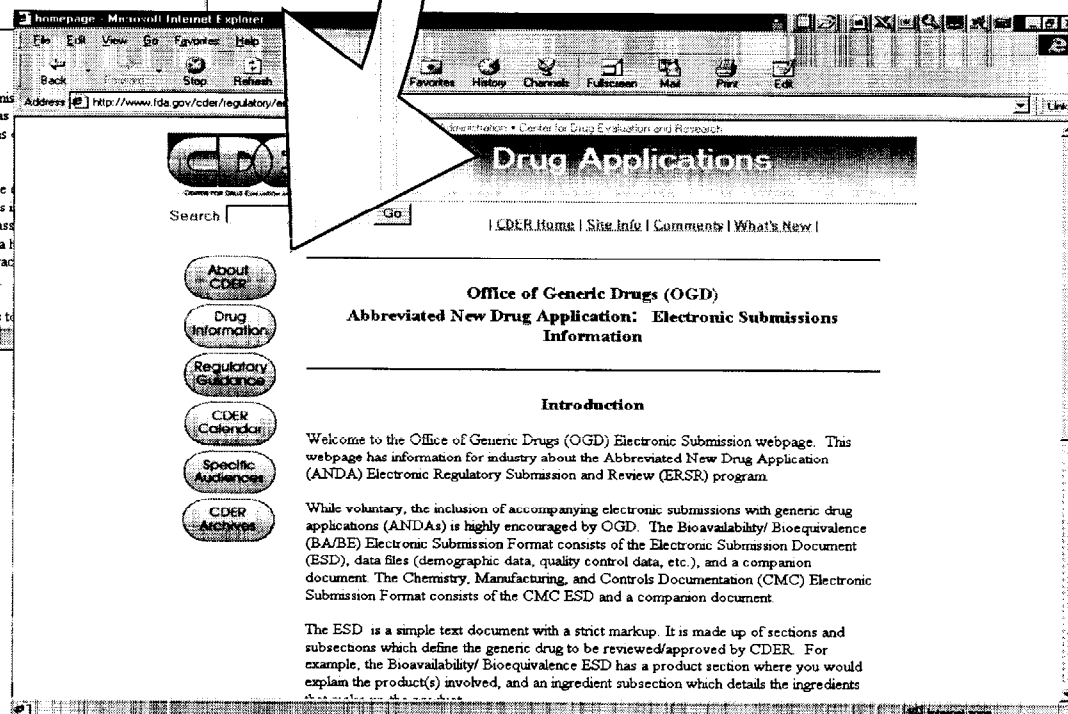


Electronic Submissions in OGD

The Web site has moved to CDER
<http://www.fda.gov/cder/regulatory/ersr/eva/>



mundos.ifsm.umbc.edu





Federal Register Notice

Docket No. 99D-5333

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration Plans to Develop
Guidance on Submitting an Archival Copy of an
ANDA in Electronic Format;**

Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.